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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,745	03/05/2002	James H. Anderson	56,493 (71699)	8461

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EXAMINER	
SAADAT, CAMERON	
ART UNIT	**PAPER NUMBER**
3714	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,745	ANDERSON ET AL.	
	Examiner	Art Unit	
	Cameron Saadat	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 17-50, 55-56* is/are rejected.

7)☒ Claim(s) *51-54 and 57-66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/24/2007 has been entered. Claims 1-15, 17-66 are pending in this application. Claim 16 is cancelled.

Claim Objections

Claims 54, 59, and 61 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the phrase "any of claims ..." should be replaced with -- any one of claims ...--.

Regarding claims 51-53, and 57, it is the examiner's opinion that the clarity and precision of the claim language can be improved by replacing "determining the physical properties" with -- determining physical properties --. See claim 51, line 15; claim 52, line 14; claim 53, line 14; and claim 57, line 11. Claims 54 and 58-66 are objected to for incorporating the above errors from their respective parent claims by dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless —
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 9-15, 17-20, 22-23, 25-26, 28-38, 40-42, 44-45, 47-50, and 55-56 are rejected under 35 U.S.C. 102(b) as anticipated by Cai et al. - Parametrical Modeling Based Multi-Layered Approach for Design and Validation of Catheterization Devices (published June 1998); hereinafter Cai.

Regarding claim 1, Cai discloses a system for designing a medical device for accessing a body cavity or lumen of a patient comprising: providing data relating to a three-dimensional geometric model of the cavity or lumen to a system comprising a knowledge base, wherein the system performs an analysis using the provided data; and obtaining a recommendation from the system based on the analysis, the recommendation relating to the geometry of a device for placement into the cavity or lumen. See p. 32-34.

Regarding claim 29, Cai discloses a system for designing a medical device for accessing a body cavity or lumen of a patient, comprising a plurality of shape knowledge base comprising: a plurality of geometries for at least one segment of a device; and rules for determining correspondence between a geometry of at least one segment and at least a portion of a model of the body cavity or lumen See p. 32-34.

Regarding claims 2, 30 and 49, Cai discloses a device shape knowledge base comprising a plurality of geometries for at least one segment of a device and rules for determining correspondence between a geometry of at least one segment and at least a portion of the model of the body cavity or lumen. See p. 33, col. 2.

Regarding claims 3 and 31, Cai discloses a three-dimensional geometric model of the cavity or lumen is obtained from a volume image of the cavity or lumen. See p. 34, Col. 1.

Regarding claims 4, 32 and 50, Cai discloses a volume image obtained from computer tomography scanning device. See id.

Regarding claim 5, Cai discloses a knowledge base comprising data relating to a physical property of the cavity or lumen. The system includes data describing physical shape the patient's vasculature. See p. 33, Col. 2, ¶ 4.

Regarding claims 7 and 33, Cai discloses a recommendation from the knowledge base that is displayed on an interface of a user device connectable to a network. See p. 33, Col. 2, ¶ 2.

Regarding claims 9 and 36 Cai discloses selectable options corresponding to design parameters of the device are transmitted to, and displayed on, the interface of the user device from the knowledge base. See p. 35, Fig. 2.

Regarding claims 10 and 41, Cai discloses selectable options that are selected from the group consisting of: shape, material, flexibility, shape memory, stiffness, softness, pliability, stability, strength, contrast medium flow rate, length, size, and combinations thereof. See P. 32, Col. 2, ¶ 3.

Regarding claims 11 and 34 Cai discloses selectable options that are selected and the system simulates the design of the device based on the one or more selected options or parameters. See p. 33, Col. 2.

Regarding claim 12, Cai discloses a device selected from the group consisting of a catheter, a guidewire, a surgical device, a balloon, a balloon-inflating devices, a coils, a stents, stent-grafts, an endoscopes, a laparoscopes, a bronchoscopes, vascular occlusion devices, optical probes, and drug delivery device are equivalents known in the art for the same purpose of performing minimally invasive surgery. See p. 33, Col. 2.

Regarding claim 13, Cai discloses that the design of more than one device is simulated. See p. 33, Col. 2 – p. 34, Col. 1,

Regarding claim 14, Cai discloses that the parameters selected for one of the devices is based on parameters of at least one of the other devices. See p. 33, Col. 2 – p. 34, Col. 1,

Regarding claim 15, Cai discloses a medical device designed to access a lumen which is a blood vessel. See p. 32, Col. 2, ¶ 3.

Regarding claim 40 Cai discloses selectable options corresponding to design parameters of the device that are transmitted to and displayed on a user interface based on data relating to the geometry of the cavity or lumen. See p. 33, Col. 2.

Regarding claims 17 and 37, Cai discloses a device comprising multiple segments and parameters of one or more of the multiple segments are selected independently. See p. 33, Col. 2.

Regarding claim 18 Cai discloses a device selected from the group consisting of a catheter, a guidewire and a surgical device, a balloon, a balloon-inflating devices, a coils, a stents, stent-grafts, an endoscopes, a laparoscopes, a bronchoscopes, vascular occlusion devices, optical probes, and drug delivery device are equivalents known in the art for the same purpose of performing minimally invasive surgery. See p. 33, Col. 2.

Regarding claim 19, Cai discloses at least one segment selected from the group consisting of a tip, a rod element, a hook element and a hub. See p. 33, Col. 1, ¶ 3.

Regarding claim 20, Cai discloses two segments having varying material properties. See p. 33, Col. 1, ¶ 3.

Regarding claims 22, 42 and 44, Cai discloses performing one or more feature operations to modify the recommended geometry. See p. 33, Col. 2.

Regarding claims 23 and 45, Cai discloses feature operations selected from the group consisting of shape sweeping, extruding, holing, braiding, edge rounding, and hub construction. See p. 33, Col. 1, ¶ 3.

Regarding claims 25, 35 and 47, Cai discloses a knowledge base including clinical information relating to the patient. See p. 34, Col. 1.

Regarding claims 26 and 48, Cai discloses device geometry determined using Finite Element Analysis. See p. 34, Col. 1.

Regarding claim 28, Cai discloses a method wherein the patient has a pathology affecting the structure of the body cavity or lumen. See P. 33, col. 2, last ¶.

Regarding claim 38 Cai discloses, a device materials knowledge base comprising a plurality of data files relating to device materials and rules for determining suitability of a device material for at least one segment of the device. See p. 32, Col. 2.

Regarding claims 55-56, Cai discloses a method further comprising: generating a geometric model of the body cavity or lumen from the provided data; and wherein said obtaining a recommendation from the system further includes obtaining a recommendation of a geometry, topology and physical properties of one or more devices for placement into the cavity or lumen using the generated geometric model. See p. 34, Col. 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai in view of Anderson et al. - Virtual Reality in Interventional Radiology; Min Invas Ther & Allied Technol; 1997; Vol. 6 (hereinafter Anderson).

The surgical planning system disclosed by Cai does not describe modeling the physical property of elasticity of the cavity or lumen. Anderson discloses an analogous system in which deformations and distentions of blood vessels are modeled. See p. 115. In view of Anderson, it would have been obvious to an artisan to modify the surgical planning system disclosed by disclosed by Cai, to add the feature of

modeling the physical property is the elasticity of the cavity or lumen. As suggested by Anderson, the modification would enhance the system by improving its performance in simulating procedures performed within a patient's venous system. See Anderson, p. 115.

Claims 8, 21, 24 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai in view of DiGioia, III et at. U.S. 6,205,411 B1; hereinafter DiGioia.

Regarding claims 21, 24, and 43, Cai does not describe determining the best fit between the geometry of the device and the geometry of a path. DiGioia discloses an analogous surgical planning system which determines the best fit between a patient's anatomy and a custom-made tool for insertion into the patient. See col. 2:56-62; 4:66-5:11, 7:64-67. In view of DiGioia, it would have been obvious to an artisan at the time of the invention to modify the surgical planning system disclosed by Cai, wherein the system assists surgeons in the design and selection of tools relative to a patients vasculature, to add the feature of determining best fit between the geometry of the device and the geometry of a path. As taught by DiGioia, the modification would enhance the system by allowing the design of tools with the proper size and geometry for a particular patient's anatomy. See DiGioia, col. 2:56-62; 4:66-5:11, 7:64-67.

Regarding claim 8, Cai discloses all of the claimed subject matter with the exception of explicitly disclosing the feature of providing a recommendation in the form of a three-dimensional representation of the medical device. However, DiGioia discloses an analogous surgical planning system which See Figs. 5, 7a-e. In view of DiGioia, it would have been obvious to an artisan at the time of the invention to modify the surgical planning system disclosed by Cai, wherein the system assists surgeons in the design and selection of tools relative to a patients vasculature, to add the feature of presenting recommended medical devices in three-dimensional form, thereby determining best fit between the geometry of the device and the geometry of a path. As taught by DiGioia, the modification would enhance the system by

allowing the design of tools with the proper size and geometry for a particular patient's anatomy. See DiGioia, col. 2:56-62; 4:66-5:11, 7:64-67.

Claims 27 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai in view of Ulug, U.S. 4,918,620.

Cai does not disclose displaying a rule used for making the recommendation in response to a query. Ulug discloses an expert system that displaying a rule used for making the recommendation in response to a query in order to allow a user to verify the veracity of the rule. See col. 3:3-51. In view of Ulug, it would have been obvious to an artisan at the time of the invention to modify the surgical planning system disclosed by Cai, wherein the system assists surgeons in the design and selection of tools, to add the feature of displaying a rule used for making the recommendation in response to a query. As taught by Ulug, the modification would enhance the system by allow a user to verify the veracity of a rule. See id.

Allowable Subject Matter

Claims 51-54 and 57-66 are allowable, however are objected to for having minor informalities. The following is an examiner's statement of reasons for allowance: Patentability is seen in, although not limited to: independent claims 51, 52, 53, and 57, the combination of elements specifically claimed including the feature of providing a diagnostic and pathological information knowledge base, wherein patient data is input into the diagnostic and pathological information knowledge base. The closest prior art of record does not teach or fairly suggest this feature in the combination. Cai does not disclose the feature of inputting patient data into a diagnostic and pathological information knowledge base. In addition, CathWorks discloses a system that provides assistance for selecting appropriate products in relation to anatomical vasculature segments and blood vessel diseases (See P. 1), however, does not disclose or suggest the feature of inputting patient data into a diagnostic and pathological information knowledge base.

Response to Arguments

Applicant's arguments filed 1/24/2007 have been fully considered but they are not persuasive. Applicant emphasizes that Cai does not disclose a knowledge base, but instead discloses a database system wherein information is stored in the database and where needed specific data can be retrieved by the database. The examiner disagrees. Cai does not merely disclose a database, but additionally discloses a parametrical modeling technique wherein a recommendation is provided by optimizing parameter values (such as material properties, size, and shape, see p. 33, col. 1, last paragraph) based on given constraints (See P. 33, Col. 2). If the system described in Cai were solely a database system, as purported by applicant, then optimization of parameters would not be possible.

Applicant's definition of a knowledgebase is a data structure comprising facts and rules. See applicant's specification, p. 7, lines 6-9. Accordingly, Cai teaches a knowledge base by optimizing parameter values based on given constraints. However, it is additionally noted that claims are given their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Applicant further emphasizes that a "rule" in a knowledge base refers to a statement associated with a certainty factor. Again, it is noted that limitations appearing in the specification but not recited in the claim are not read into the claim.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- **CathWorks** (A CAD-integrated and Feature-based System for Designing, Presenting and Validating Catheterization Devices) Version 12, August 1999 – discloses a system that provides

assistance for selecting appropriate products in relation to anatomical vasculature segments and blood vessel diseases.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is (571) 272-4443. The examiner can normally be reached on M-F 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cameron Saadat
Patent Examiner
Art Unit 3714
March 28, 2007